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FACT

FOOD ANIMAL CONCERNS TRUST
411 W. FULLERTON PARKWAY, #1402W
POST OFFICE BOX 14599
CHICAGO, ILLINOIS 60614

Docket No. 03-0801
Regulatory Analysis and Development
PPD, APHIS
Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

April 6, 2004

Please find the enclosed comments from Food Animal Concerns Trust on the Proposed Rule Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities. This is our second submission of comments on this rule. We previously submitted comments on January 2, 2004. These comments supercede those submitted at the earlier date.

Sincerely,



Steven Roach
Food Safety Program Manager

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PHONE (773) 525-4952 FAX (773) 525-5226

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PPD, APHIS
Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

Comments from Food Animal Concerns Trust (FACT) in response to
the United States Department of Agriculture's (USDA) Proposed Rule
Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of
Commodities

Comments submitted by
Richard Wood, Executive Director and Steven Roach, Food Safety Program Manager

April 6, 2004

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. Since Bovine Spongiform Encephalopathy (BSE) was first recognized in the mid 1980s, FACT has worked diligently with Federal regulatory agencies to develop an appropriate response to the threat to human and animal health presented by this fatal degenerative disease.

FACT welcomes this opportunity to provide comments on the proposed rule, *Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities*, that would allow the importation of live cattle and animal products from countries with cases of BSE. FACT believes that it is important to periodically review the steps taken to reduce the risk of BSE from imported livestock and animal products as new scientific research helps us to better understand this deadly disease. However, FACT believes that the proposed rule does not provide the definitive criteria needed to determine if importing cattle from a country with a BSE case is truly a minimal risk.

FACT believes that it is wrong to consider Canada a minimal risk region at this time given the information that is currently available. It is important to acknowledge that with limited surveillance in both the U.S. and Canada, two cases of BSE have been detected and have been linked to animal feeding in Canada. The surveillance has been "limited" because it is unclear in both the U.S. and Canada what level of incidence of disease the surveillance was reasonably expected to detect. The likely incidence level is apparently more than one in a million given the large numbers of high-risk animals, dead-on-farm or downers, not captured in the surveillance programs of each country. While both of the North American indigenous BSE cases were born before the feed bans were put into place, this does not indicate that the ban was effective. Given the long incubation period for BSE, it may be that cattle infected after the ban are only now reaching an adequate age to be detected. With increased surveillance and more time, the effectiveness of the ban will become more clear. What the two indigenous cases do indicate is that import controls were not adequate in Canada to prevent the introduction of the disease. This means that the first line of defense against BSE was breached, and the control of the disease was dependent of the effectiveness of the feed ban.

FACT believes that the existing US Department of Agriculture regulation that prohibits the importation of live ruminants and ruminant products from countries with indigenous BSE cases already adequately protects public health. FACT believes that the proposed rule is not in response to new science, but is instead a response to the detection of BSE in a major trading partner and in the expectation that a U.S. born case may soon be detected.

As far as we know, the latest science on BSE is that the infective dose for cattle is smaller than previously believed (Detwiler, 2003) and that there may be additional strains which may be responsible for previously unrecognised human disease (Castelone et al., 2004).

If the USDA goes forward with a rule for creating a minimal risk region, FACT recommends that it include clear criteria. The proposed rule acknowledges the guidelines proposed by the Office International des Epizooties (OIE), but then rejects the approach of the OIE to require specific criteria. Instead the proposed rule is based on “evaluating the overall combined effect of the factors” without stating necessary criteria for each factor. While it is important to consider the factors together, clear criteria are also important. These clear criteria are lacking from the proposed rule. FACT is concerned that the focus on general factors as opposed to clear criteria in the proposed rule do not protect public health. They also could open the U.S. to charges of arbitrarily placing barriers to free trade in the future, or if adopted by other countries could be used to block U.S. access to foreign markets.

FACT recommends that for a country with an indigenous case of BSE within the last 7 years to be considered a “minimal risk region” the following criteria be met.

- 1) There is a sufficient surveillance system in place to detect a prevalence in the country of at least one in a million and that the detected prevalence for at least the last four consecutive 12 months has been less than one in a million. If the surveillance system is targeted to at-risk animals, downers and dead on farm, the

sample of these animals must be large enough and random enough to detect the one in the million prevalence. If it is not possible to get an adequate sample of dead and downer animals, the sampling population must include all adult animals.

This criteria is based on the OIE standards, but addresses the inadequacy of current OIE surveillance recommendations. Clearly the OIE recommendations for surveillance are unrealistic given that Canada, with a cattle population over 5 million adult cattle, would only need to sample 433 cattle. At the sampling levels recommended by OIE, Canada would not have detected its indigenous case.

The proposed USDA rule fails to include any incidence rate as part of the criteria for inclusion in "a minimal risk region." The proposal also only requires that surveillance exceed the OIE requirements. By failing to set an incidence level and a requirement for surveillance sufficient to detect that level, the proposed rule leaves open the possibility that a country with a high but undetected level of BSE could be allowed to export animal products and live ruminants to the U.S.

- 2) There must be compulsory notification and investigation of all cattle showing clinical signs compatible with BSE. This is consistent with the OIE Terrestrial Animal Health Code and helps to address some of the challenges to surveillance.
- 3) The ban on feeding ruminants with meat and bone meal has been effectively enforced for at least 8 years. The proposed rule considers this recommendation by

the OIE, but rejects it stating that no set number of years is necessary if other steps are taken. FACT believes that given the long incubation period for BSE, the criteria for eight-years is prudent. In respect to Canada, this means waiting only one more year and would allow time to see if the additional steps that have been put in place after the indigenous case was detected are working.

In the proposed rule, it states that there must be “no evidence of significant noncompliance of the ban.” FACT believes that the lack of evidence is not an adequate criteria unless there is a program in place to collect that evidence. A feed testing program should be required to ensure that the ban is working. FACT is concerned that the feed ban in both the U.S. and Canada has been mainly an exercise in record keeping without a sufficient number of process controls. FACT urges that for a country to be considered a minimal risk region, relevant authorities must have a feed testing program in place to ensure that the ban is working. Annual visits to feed plants alone do not constitute an effective feed ban.

- 4) An effective animal identification system must be in place which keeps information on livestock age with the animal.
- 5) Additional mitigation measures taken after the detection must include the removal of Specified Risk Materials (SRMs) from all livestock feeds and the banning of all mammalian and poultry proteins except milk from ruminant diets. These steps are

consistent with the recommendations of the International Review Panel reports after both the Canadian and U.S. case were detected.

FACT opposes adding Canada to the category of regions considered at minimal risk for BSE. First, given that we have two cases of BSE in cattle born in Canada and most likely exposed to BSE in Canada, there is indisputable evidence that restrictions on the importation of animals and feed has not been adequate to protect the region. Second the feed ban has not been in force for a long enough period to ensure that other cases will not be detected. Finally, Canada has tested less than 8,000 cattle overall despite having a population of over 5 million cattle. Until we have more information about the prevalence of BSE in the Canadian cattle herd, it is folly to allow the import of live ruminants and ruminant products from Canada. Once the prevalence of the disease has been determined and if it is less than one in a million then we could reconsider allowing imports of Canadian ruminants and ruminant products.

FACT recommends that the USDA hold public hearings before going forward with this important change in the manner in which we protect our borders from BSE. These public hearings should not only be held in Washington D.C., but should also be held in other regions of the country to ensure maximum participation. FACT believes that allowing the importation of livestock and animal products from countries with BSE is an important enough change to require further public discussion.

In conclusion, FACT believes that the proposed rule should be withdrawn or at least drastically modified. Protecting our borders from BSE is the first step to protecting our livestock industry and the American public from this deadly disease. If we are to open up the borders, it should only be based upon the exporting country providing sufficient information to show that there really is a minimal risk. The criteria listed above by FACT would increase the likelihood that sufficient information would be available to determine that the risk truly is minimal.

References cited:

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